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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,828	12/21/2001	Ticcheng A. Qiao	82917WFN	4935

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06/21/2004

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,828

Applicant(s)

QIAO ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 April 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 1 April 2004 in which claims 1, 6-7 and 21 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 5 January 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-25 are under prosecution.

Claim Objections

3 Claim 21 is objected to because of the following informalities: The claim is objected to because, in line 11, "contacting" is misspelled "contracting". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 are indefinite in Claim 1, line 11 for the recitation "the color barcode" because the recitation lacks proper antecedent basis in the "optical barcode" of line 8.

Claims 5-7 are indefinite in Claims 5 and 7 for the recitation "color signature/barcode image" because it is unclear whether the claim is limited to alternatively "color signature" or "barcode image". The recitation is further indefinite because "color signature" and "barcode image" both lack antecedent basis in the microspheres having "optical barcode" of Claim 1.

Claims 21-25 are indefinite in Claim 21, line 12 for the recitation "the color barcode" because the recitation lacks proper antecedent basis in the claim.

Claims 21-25 are indefinite in Claim 21 for the recitation "color signature/barcode image" because it is unclear whether the claim is limited to alternatively "color signature" or "barcode image".

Claims 21-25 are indefinite in Claim 21, line 11 for the recitation "said array" because the recitation lacks proper antecedent basis in the "microarray" of line 3.

Claims 21-25 are indefinite in Claim 21, step (c) line 2 for the recitation "identification of said identification of said biological sample" because "of said identification" is confusing.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 8-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Guire et al (U.S. Patent Application Publication No. 2003/0073086 filed 5 October 2001).

Regarding Claim 1, Guire et al discloses a method for detecting biological samples comprising providing a microarray including a composition of microspheres dispersed in a fluid containing a gelling agent (i.e. slurry ¶ 88 and 97-98) and immobilized at random position on the substrate (¶ 38) wherein the substrate does not have preselected microsphere sites (i.e. substantially flat, ¶ 37) and wherein the microspheres contain an optical barcode generated from at least one colorant and further contain a biological probe (¶ 46-51). Guire et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 1 and Example 4).

Regarding Claim 2, Guire et al disclose the method comprising a plurality of sub-populations, each comprising a unique optical barcode and probe (Claim 8).

Regarding Claim 3, Guire et al disclose the method wherein the barcode is generated by two colorants i.e. Texas Red/Bodipy (¶ 134).

Regarding Claim 4, Guire et al disclose the method wherein the barcode is generated by a mixture of red, green and blue colorants (i.e. dye combination, ¶ 51 and ¶ 135).

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Regarding Claim 8, Guire et al disclose the method wherein the substrate is characterized by an absence of specific sites capable of interacting with the microspheres (§ 35-37).

Regarding Claim 9, Guire et al disclose the method wherein the microsphere has active sites with probes (pp63).

Regarding Claims 10-12, Guire et al disclose the method wherein the microspheres have a diameter of between 5 and 20µm i.e. 10µm (§ 39 and 155).

Regarding Claims 13-15, Guire et al disclose the method wherein the microspheres are immobilized at a concentration of between 10,000 and 100,000/cm² (§ 152).

Regarding Claim 16-18, Guire et al disclose the method wherein the microspheres comprise amorphous polystyrene (§ 40).

Regarding Claim 19, Guire et al disclose the method wherein the microspheres comprise a polymeric material (§ 40) and less than 30% weight crosslinking material i.e. 1mg/ml microparticle and 0.05-0.25mg/ml DSS (Example 2, § 141-144).

Regarding Claim 20, Guire et al disclose the method wherein the microspheres are prepared by emulsion polymerization (§ 55).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-7 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire et al (U.S. Patent Application Publication No. 2003/0073086 filed 5 October 2001) in view of Porter et al (U.S. Patent No. 6,146,899,

Regarding Claims 5-7 and 21-25, Guire et al discloses a method for detecting biological samples comprising providing a microarray including a composition of microspheres dispersed in a fluid containing a gelling agent (i.e. slurry ¶ 88 and 97-98) and immobilized at random position on the substrate (¶ 38) wherein the substrate does not have preselected microsphere sites (i.e. substantially flat, ¶ 37) and wherein the microspheres contain an optical barcode generated from at least one colorant and further contain a biological probe (¶ 46-51). Guire et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 1 and Example 4) wherein the processing utilizes a pattern recognition algorithm (¶ 110).

Guire et al further teach the microspheres have luminescent or fluorescent properties (e.g. ¶ 51-53) wherein detecting comprises whole frame imaging (Fig. 5) and image processing using detection methods known in the art and combinations of the detection methods (¶ 135 and 162) but they do not specifically teach whole frame capture to produce a first image and whole frame capture under bright field illumination.

However, bright field illumination coupled with a first image collection was well known in the art at the time the claimed invention was made as taught by Porter et al who teach that bright field illumination for additional image collection facilitated focusing while minimizing photobleaching (Column 4, lines 57-62). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the confocal illumination of Guire et al with the additional bright field illumination taught by Porter et al for the expected benefit of focusing the image while minimizing photobleaching as taught by Porter et al (Column 4, lines 57-62).

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Regarding Claim 22, Guire et al teaches the method wherein the processing utilizes a pattern recognition algorithm (§ 110)

Regarding Claim 23, Guire et al disclose the method comprising a plurality of sub-populations, each comprising a unique optical barcode and probe (Claim 8).

Regarding Claim 24, Guire et al disclose the method wherein the barcode is generated by two colorants i.e. Texas Red/Bodipy (§ 134).

Regarding Claim 25, Guire et al disclose the method wherein the barcode is generated by a mixture of red, green and blue colorants (i.e. dye combination, § 51 and § 135).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 21-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 of copending Application No. 10/098,642. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar methods of identifying biological samples and differ only in the instant claims define the

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coating composition as comprising a gelling agent. However the '642 specification and Claims 1-20 define their preferred embodiment comprise a gelling agent. Hence, the instantly claimed method would have been obvious in view of the '642 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BJ Forman, Ph.D.
Primary Examiner
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June 17, 2004